## REMARKS

Claim 39 has been canceled. In view of the foregoing amendments, Claims 1, 2, 12, 32, 33, 37, 40, and 114-116 are pending in the above application. The changes made to the claims by the current amendment, including ~~deletions~~ and additions, are shown herein with deletions designated with a strikethrough and additions underlined. No new matter has been added herewith.

**Rejection under 35 U.S.C. §112, first paragraph (New Matter)**

The Examiner has rejected claims 37, 39 and 40 as containing new matter because the Examiner does not believe that there is support for the following amendments to the claims: Claim 37 "further comprises a second peptide or protein from *L. intracellularis*"., Claim 39 "wherein the second peptide or protein is in recombinant form", and Claim 40 "wherein the second protein is selected from the group consisting of: a refolding protein, a second heatshock protein, ....". Claim 37 has now been amended and Claim 39 canceled. Support for the claims as presently amended is described below.

Claim 37 has been amended to recited that the vaccine composition comprises "more than one immunogenic component from *L. intracellularis*." This language is specifically supported in Applicants' specification at page 4, line 25, where it is stated that the vaccine composition comprises "an amount of ***at least one*** immunogenic component from *L. intracellularis,*" since "at least one" is simply another way to state "one or more." Moreover, Example 20, beginning on page 30 of the specification, provides a method for identifying various immunogenic components as a refolding protein, a flagellar basal body rod protein, S-adenosylmethionine, a tRNA ribotransferase-isomerase, an autolysin, an enoyl-(acyl-carrier-protein) reductase or a glucarate transporter, as recited in Claim 40. Thus, Applicants respectfully request withdrawal of the new matter rejection in view of the clear support in the specification for the amended claims.

**Rejection under 35 U.S.C. §112, first paragraph (Enablement)**

The Examiner has rejected Claims 32, 33, 37, 39, 40 and 114-116. The Examiner does not believe that the specification is enabling for the following: (a) the composition containing the heatshock protein of SEQ ID NO:2 and "a second protein" and (b) a method of using the composition with the "second protein" to treat an animal already infected. The claims have been

amended to clarify that the vaccine can comprise one or more immunogenic components. In addition, as stated above, the specification clearly teaches more than one immunogenic component.

With respect to the relative skill of the artisan and the experimentation necessary, it is clear that those who are skilled in the art of vaccination possess an advanced skill at identifying proteins which would be useful to include as a second peptide or protein. The vaccination arts are one of the oldest and most widely studied. Thus, although there is no specific working example which includes more than one immunogenic component, it would require a minimum of experimentation to practice the claimed invention. It would require the skilled artisan to simply add another immunogenic component to the vaccine. The effective amount would likely be very close to the same amount needed for the protein of SEQ ID NO:2. The quantity of experimentation necessary for the skilled artisan to perform the step of adding a second protein or peptide is minimal, particularly when the specification sets out specific proteins and/or peptides which can be used.

With respect to the method of treating, the Examiner states that there is nothing in the Specification suggesting that the vaccine composition could be used to treat a patient already infected with *L. intracellularis*. The Examiner believes that, although the specification on page 3, line 18 teaches that the vaccine can be used to treat an infected patient, there is no specific example showing that such a treatment was efficacious. However, enablement does not require experimental evidence to prove that a vaccine composition is effective. Particularly in a case such as this when one of skill in the art knows that currently, many vaccines that are administered post-infection are being used very successfully for treatment of many chronic and slow-acting disease (such as rabies). As stated in the MPEP §2164.02, "Compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic."" And "The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. In re Barkowski, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970)." In the present patent application, the method of immunizing an animal (se Claim 32) pre-infection is enabled. Then it follows that the method of treating an animal with a vaccine post-infection is also enabled. It is clear that undue experimentation would not be necessary to vary the method of immunization pre-infection for a

post-infection treatment. In fact, the type of vaccine, the amount of vaccine, and the treatment schedule would likely be very close if not identical to that for a pre-infection vaccine.

The Examiner does not believe that the recitation of the specific *L. intracellularis* proteins is enabled because the proteins were determined using sequence similarity of the SEQ ID NOS: 4, 7, 8, 10, 11, 13, 14, 16-20, and 22-27 and an enzymatic activity and/or use as "putative" vaccine candidates is not enabled. As stated above, "Compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether an example is disclosed" meaning that an actual working example of the protein and its use in immunization is not necessary. This is because the sequence similarity is enough for identification of the proteins of these SEQ ID NOS in view of the state of the art. The ability to predict that activity of a protein by sequence similarity is quite advanced in the art using a variety of computer programs. These programs can predict with a high certainty the type of enzymatic activity that will result. In addition, the proteins were identified using antisera from a pig vaccinated with *L. intracellularis* (see Example 14). The pigs that were vaccinated in this way showed no signs of the disease (PPE, see Example 16). This provides clear evidence that the proteins which were identified using antibodies from these pigs are immunogenic and can be used as a component of a vaccine. Thus, Applicants believe that it would not require undue experimentation for one of skill in the art to identify the specific proteins (flagellar basal body rod protein, refolding protein, autolysin) from *L. intracellularis* as claimed in Claims 40 and 116 with the direction provided in the specification. The specification provides the actual sequence of many of these proteins. In addition, the specification provides clear data that the specific proteins are immunogenic and, thus, useful as a component of a vaccine containing GroEL.

In view of the arguments and amendments, Applicants respectfully request withdrawal of the enablement rejections.

**Rejection under 35 U.S.C. §112, second paragraph**

The Examiner has rejected Claims 1, 2, 12, 32, 33, 37, 39, 40 and 114-116 as being indefinite for the following reasons:

Claim 1 is believed indefinite for the recitation "heatshock protein ....having an amino acid sequence comprising SEQ ID NO:2, L. intracellulari (and L. intracellularia), and "induce an immune response". Applicants have amended the claim to read --heatshock protein comprising

the amino acid sequence of SEQ ID NO:2--, and --*L. intracellularis*--. In addition, Claim 1 has been amended to specify to whom the immune response is being induced. Applicants respectfully request withdrawal of the indefiniteness rejection.

Claim 12 is believed indefinite for the recitation "a nucleic acid having a sequence comprising SEQ ID NO:1." The claim has been amended as suggested by the Examiner to read --a nucleic acid having the nucleotide sequence of SEQ ID NO:1--.

Claim 32 is believed indefinite for the term "effective". The claim has been amended to read --in an amount effective to induce an immune response to *L. intracellularis*--.

The Examiner objected to Claims 37 and 40 for containing a comma after the recitation of "protein" and for including a dash in the recitation "the-second". These minor informalities have been corrected herein.

Claims 40, 114, 115, and 116 are believed vague and indefinite and/or confusing by the Examiner in the recitation of "protein...selected from the group consisting of ...". The Examiner does not believe that SEQ ID NO: 7 which is 12 amino acids long, SEQ ID NO:16 which is 3 amino acids long, SEQ ID NO:20 which is 9 amino acids long, SEQ ID NO:19 which is 11 amino acids long, SEQ ID NO:23 which is 2 amino acids long, and SEQ ID NOS:5 and 6 which are 5 amino acids long, SEQ ID NO:23 which is 2 amino acids long, SEQ ID NO:16 which is 3 amino acids long, SEQ ID NO:25 which is 7 amino acids long, and SEQ ID NO:26 which is 5 amino acids long is a protein. Claim 40 has been amended to simply recite "immunogenic composition, and the other claims amended to recite a "peptide".

The Examiner has rejected Claim 116 as indefinite. However, the claim merely lists proteins which are identified in Example 20. The recitation of these specific proteins can be determined using the method described in that example. Applicants respectfully request withdrawal of this rejection.

Claim 114 is believed indefinite by the Examiner for the recitation "polypeptide selected from the group consisting of: SEQ ID NOS:..." since the recited SEQ ID numbers represent amino acid sequenced. The claims has been amended as suggested by the Examiner to read: --polypeptide comprising the amino acid sequence selected from the group consisting of SEQ ID NO:...--, thus rendering the claim definite.

Claim 115 is believed vague or indefinite for the recitation of "a single protein of SEQ ID NOS: 12, 15..." because the Examiner does not believe that these sequences encode a single protein. The claims have been amended to read –a single protein or peptide--.

Claims 40 and 116 are believed vague and indefinite by the Examiner for the recitation of "an S-adenosylmethionine, tRNA ribosyltranferase-isomers". The added comma was simply a typographical error and has been removed in the Claim amendments, rendering the claims definite.

In view of the Claim amendments and arguments, Applicants respectfully request withdrawal of the indefiniteness rejections.

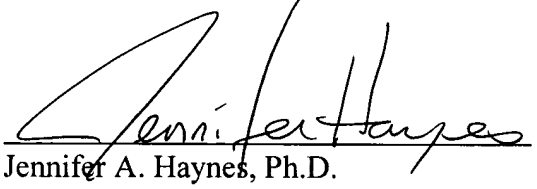
**Conclusion**

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 31, 2005

By: 

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